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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,298	08/28/2001	Dominic A. Dragotta	CL1598 US NA	5133

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/03/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,298

Applicant(s)

DRAGOTTA ET AL.

Examiner

Ralph Gitomer

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Applicant's election without traverse of Group I, claims 1-12, in Paper No. 8 is acknowledged. The IDS's received 12/3/01 and 5/20/02 have been entered and considered. The priority date is granted to 9/8/2000.

It appears the point of novelty of the present invention is correlating PHA to control cultures within a bioreactor by adjusting feed nutrients to keep PHA in a desired range.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103[®] and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of Brdjanovic and Lee in view of Chuang.

Brdjanovic (Water Science Technology) entitled "Bioassay for Glycogen Determination in Biological Phosphorus Removal Systems" teaches on page 541 last paragraph bridging to page 542, phosphorus removing bacteria store nutrients as PHA and polyhydroxybutyrate. On page 542, glycogen determination is less reliable than PHA for glycogen determination.

Lee (Waste Management) entitled "Production and Degradation of Polyhydroxyalkanoates in Waste Environment" teaches on page 133, PHA is the storage material accumulated under unfavorable growth condition and PHA production from waste has been investigated in order to utilize abundant organic compounds in waste water. On page 137 column 2 PHA accumulating microorganisms can be wisely employed in waste treatment processes as demonstrated for phosphorus removal process.

The claims differ from the above references in that they recite the PHA determination is correlated to adjusting the feed nutrients of the sludge.

Chuang (Water Science Technology) entitled "Evaluation of Phosphorus Removal in Anaerobic Anoxic Aerobic System via PHA Measurements" teaches in the abstract, to evaluate phosphorus removal, determining PHA in sludge under different conditions. The PHA content of sludge closely relates to phosphorus release and uptake behavior under anaerobic and aerobic conditions. When under a high organic loading condition, sludge exhibits a large amount of PHA. Under low organic loading conditions there are low PHA content. Organic loading should be carefully controlled for phosphorus removal. On page 108, first full paragraph, PHB and PHV are major PHA components. On page 110, the effluent concentration of phosphorus varied markedly under different organic loading conditions. On page 113 the relation between PHA and organic loading and phosphorus removal is discussed. Based on the results shown in the figures, organic loading should be carefully controlled under adequate range to remove phosphorus.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the PHA determinations of the primary references to adjust the feed nutrient in the sludge as taught by Chuang because all of the references are directed to measuring a wastewater treatment process by determining PHA. To adjust the process to optimize any parameter desired based on PHA would have been obvious over Chuang who shows the correlations between various parameters and phosphorus removal and PHA. The choice of what to add as a nutrient would have been obvious in view of the types of nutrients found in sludge.

Claims 1, 4-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for PHA, does not reasonably provide enablement for "an internal storage molecule". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim the terms "an internal storage molecule " lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such molecule would work in the instant invention.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
3. Presence of working examples are only for a single specific substance and extension to other compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related substances are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of compounds.
8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

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Claims 1-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

The preamble of claim 1 is directed to monitoring but there is no step recited to perform monitoring. There are many instances of lack of antecedent basis in the claims, for example in claim 1 "the biocatalytic efficiency".

The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Barak (Applied and Environmental Micro) teaches denitrifying bacteria.

Goronszy (5,013,441) teaches controlling nutrients in sludge systems.

Saito (5,968,801) teaches PHA.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone numbers for this Art Unit are before final (703) 872-9306 and after final (703) 872-9307. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application

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information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.



Ralph Gitomer
Primary Examiner
Group 1651

RALPH GITOMER
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